K010579

VI. 510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

(Pursuant to Section 12, Safe Medical Devices Act of 1990)

A. Submitter Information:

Name: Medtronic, Inc.
Address: 37A Cherry Hill Drive, Danvers, MA 01923
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Contact Person: Fred Boucher, Regulatory Affairs Manager

Date of Preparation: February 26, 2001

B. Device Name:

Trade Name: Medtronic® 5F and 6F Stent Support Guide Catheter
Common Name: Guide Catheter
Classification Name: Intravascular Catheter / Percutaneous Catheter

C. Predicate Device Names Cordis® Envoy™ Guide Catheter
Medtronic 5F and 6F Zuma™ Guide Catheter

D. Device Description: Medtronic Stent Support Guide Catheter.

E. Intended Use The Medtronic Stent Support Guide Catheters provide a pathway through which therapeutic devices are introduced. The guiding catheter is intended to be used in accessing the coronary, peripheral or neurovascular system.

F. Technological Characteristics Summary

1. The Medtronic Stent Support Guide Catheter is substantially equivalent to the Cordis Envoy Guide Catheter regarding components and design and the Medtronic 5F and 6F Zuma Guide Catheters regarding materials, components, design, packaging and sterilization.

2. The indications for use are identical to the Cordis Envoy Guide Catheters regarding neurovascular access and the Medtronic Zuma Guide Catheters regarding coronary and peripheral access. They are all indicated to provide a pathway through which therapeutic devices are introduced. The Medtronic Stent Support Guide Catheter indications for use are as follows:

   Medtronic Stent Support Guide Catheters are designed to provide a pathway through which therapeutic devices are introduced. The guiding catheter is intended to be used in accessing the coronary, peripheral or neurovascular system.

3. Similar to the Cordis Envoy and Medtronic Zuma Guide Caterers, the Medtronic Stent Support Guide Catheter will be available in 5F and 6F sizes and will be offered in various curve styles.

4. The Medtronic® Stent Support Guiding Catheters are constructed with a braided proximal shaft with an inner liner a secondary segment, primary segment, a sleeve and a soft distal tip. The inner lumen of the catheter has a thin lubricious coating.

5. All appropriate biocompatibility tests were successfully performed on the materials used for the Medtronic Stent Support Guiding Catheter.

6. Results of testing verified that the Medtronic Stent Support Guiding Catheters meet all applicable standards and specifications and are deemed adequate for the intended use. The guide catheters are considered to be substantially equivalent to the following device:

   - Cordis® Envoy™ Guiding Catheter (K982632)
   - Medtronic® 5F Zuma™ Guide Catheter (K990707)
   - Medtronic® 6F Zuma™ Guide Catheter (K981198)

Appendix A: Biocompatibility Testing

The Medtronic Stent Support Guide Catheters are comprised of the same materials used for the Medtronic Zuma catheters. The table below lists the testing performed on Medtronic Zuma catheters containing all materials utilized in the manufacturing of the Medtronic Stent Support Guide Catheters.
The selection of tests for the evaluation of the Medtronic 6F and 8F Zuma Guiding Catheters comply with the requirements of ISO 10993-1: 1994, *Biological evaluation of medical devices – Part 1: Guidance on the selection of tests.* All test data and reports obtained during this evaluation were reviewed and considered acceptable based upon requirements contained within ISO 10993-1.

Additional screening tests were selected to evaluate additional materials utilized in the 5F Z2 Guiding Catheter.

Guiding Catheters are categorized as external-communicating devices, circulating blood, limited exposure (≤24 hours).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 21 2001

Mr. Fred L. Boucher
Regulatory Affairs Manager
Medtronic, Inc.
37A cherry Hill Drive
Danvers, MA 01923

Re: K010579
Medtronic® 5F and 6F genius Guide Catheter
Regulation Number: 870.1250
Regulation Name: Percutaneous catheter
Regulatory Class: Class II
Product Code: 74 DQY
Dated: November 9, 2001
Received: November 13, 2001

Dear Mr. Boucher:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality

systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4586. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address
http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

James E. Dillard III
Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K010579

D. Indications For Use

Device Name: Medtronic Genius Guide Catheter

Indications for Use: The Medtronic Genius Guiding Catheter is designed to provide a pathway through which therapeutic devices are introduced. The guiding catheter is intended to be used in the coronary, peripheral or neurovascular system.

Contraindications: None

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division of Cardiovascular & Respiratory Devices
510(k) Number K010579

Prescription Use ✓ OR Over-the-Counter Use _____
(Per 21 CFR 801.109)